IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

UTILITY PATENT APPLICATION

ELECTROSURGICAL WORKING END FOR CONTROLLED ENERGY DELIVERY

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to systems and methods for delivering energy to tissue, and more particularly to systems for hyperthermic treatment or ablation of targeted tissues, such as tumors and the like. The system of the invention maintains a selected energy delivery profile in a targeted tissue volume to effectively localize thermal effects for a selected time interval.

2. Description of the Related Art

In recent years, a number of instruments have been disclosed for localized thermally-mediated treatments or ablations of tumors or other targeted tissues in an interior of a patient's body. Any such percutaneous or minimally invasive treatment offers the advantage of causing less damage to healthy tissue when compared to an open surgical procedure, for example an excision of a tumor. Further, a localized thermal treatment of a tumor can prevent seeding of the tumor which is believed to be a risk factor in an open surgery.

Several terms have been used to describe such thermally-mediated treatments, generally depending on the temperature range of the therapy, including terms such as hyperthermia, thermotherapy and ablation. Hyperthermia often is used to describe therapies that cause tissue temperatures in the range of 37° C. to about 45° C. or higher that do not

cause immediate cell disruption and death. The term ablation typically describes temperature ranges that denature proteins, such as in coagulation, for example in the 50°-100° C. range and higher. This disclosure relates to the controlled application of energy to tissue in any thermotherapy, and will typically use the terms thermally-mediated therapy or ablation to describe the methods of the invention that cover temperature ranges from about 37° C. to 200° C.

An exemplary thermally-mediated therapy of the invention is the ablation of tumors, whether benign or malignant, for example tumors of the liver. In a prior art therapy, heat has been applied to a tumor by means of direct contact of the targeted tissue with an exposed radio-frequency (Rf) electrode carried at the distal end of a insulated needle-type probe as depicted in FIG. 1A (see, e.g., U.S. Patent No. 5,507,743). The principal problem related to the use of Rf electrode needles is that the tissue volume elevated in temperature is not adequately controlled and localized. For example, it may be desirable to maintain a targeted tissue region between 65° C. and 70° C. for 300 seconds. FIG. 1A illustrates the active heating of tissue around the needle electrode at time T_1 which comprises a time interval just after the initiation of mono-polar Rf flow through the tissue (ground pad not shown). The arrows in FIG. 1A depict the application of Rf energy fairly deep into the tissue volume. Next, FIG. 1B illustrates that the active heating of tissue at time T_2 around the electrode, which is limited in depth as indicated by the arrows. In a typical treatment with a fine needle, the initial active Rf energy will dehydrate or even desiccate tissue around the needle, and probably coagulate microvasculature. The result can be an elevation of the tissue's impedance (due to lack of fluid in the tissue) that is not altered by migration of body fluids to the site. Thus, even if Rf power delivery to the tissue is modulated by a feedback mechanism, such as impedance monitoring, the lack of the fluid content in the tissue may never allow substantial *deep* active Rf energy in the tissue volume around the electrode.

What is needed is a system and method for delivery of Rf energy to targeted tissue volumes in a precisely controlled manner for localization of thermal effects. It would desirable to provide an Rf system that can maintain a selected tissue temperature, and Rf density in tissue, independent of changes in voltage or current and without the need for feedback mechanisms.

SUMMARY OF THE INVENTION

In general, the various embodiments of probes corresponding to the present invention all provide an Rf working end that is adapted to instantly and automatically modulate active Rf energy density in a targeted tissue without reliance of prior art "feedback" monitoring systems that measure impedance, temperature, voltage or a combination thereof. I an exemplary embodiment, a needle-type probe can be used for tumor ablation.

The energy delivery member of any probe of the present invention defines a tissue-engagement plane that is adapted to contact the targeted tissue. A cross-section of the working end interior of the engagement plane explains the multiple components that comprise the invention for applying energy to tissue. Typically, the engagement plane defines a thin *surface* conductive layer portion (for tissue contact) that overlies a *medial* conductive matrix of a temperature sensitive resistive material. Interior of the *medial* conductive matrix is an *inner* or core conductive material (an electrode) that is coupled to an Rf source and controller. Of particular interest, the *medial* conductive matrix comprises a positive temperature coefficient (PTC) having a resistance (i.e., impedance to electrical conduction therethrough) that changes as it increases in temperature. One type of PTC material is a ceramic that is engineered to exhibit a dramatically increasing resistance (i.e., several orders of magnitude) above a specific temperature of the material—a Curie point or *switching range.*

The working end of the invention utilizes a medial variable conductive matrix that has a selected switching range, for example a narrow 2°-5° C. range, which approximates the target temperature of the thermally-mediated therapy. In operation, it can be understood that the engagement plane will apply active Rf energy to the engaged tissue until the medial conductive matrix is heated to the selected switching range. When the tissue temperature thus elevates the temperature of the medial PTC conductive layer to the switching range, Rf current flow from the core conductive electrode through to the engagement surface will be terminated due to the exponential increase in the resistance of medial conductive matrix. This instant and automatic reduction of Rf energy application can be relied on to prevent any substantial dehydration of tissue proximate to the probe's engagement plane. By thus maintaining an optimal level of